

REMARKS

Applicants thank Examiner Berch for the telephonic interview held on November 18, 2005 with the Applicants' representative, Eugenia Garrett-Wackowski. During the telephonic interview, a number of issues were discussed and a number of amendments were proposed that have helped Applicants to address more fully the concerns of the Examiner. The issues discussed during the telephonic interview are set forth below as well as in the Interview Summary mailed February 3, 2006. Applicants thank Examiner Berch for his time and his consideration of the issues.

Upon entry of the present Amendment, claims 1-42 and 44-46 are pending in the above-referenced patent application and are currently under examination. Moreover, upon entry of the present Amendment, the specification, the abstract and claim 1 have been amended as discussed in more detail below. No new matter has been added. Accordingly, Applicants request entry of the present Amendment and reconsideration of the application.

The claims are rejected in various combinations under 35 USC § 112, first paragraph, for written description and enablement, as well as under § 112, second paragraph, for indefiniteness. Each of these rejections is addressed below in the order set forth in the Office Action.

Applicants acknowledge, with appreciation, the Examiner's indication that claims 10 and 36-41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

I. WRITTEN DESCRIPTION REJECTIONS UNDER 35 USC § 112, FIRST PARAGRAPH

Claims 1-3, 6-7, 11-35, 42 and 44-46 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully traverse the rejection.

The test for written description is whether the specification describes “the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.” *See, e.g., Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116-17. “The subject matter of the claim need not be described literally (i.e., using the same terms or in *haec verba*) in order for the disclosure to satisfy the description requirement.” (MPEP §§ 2163, 2163.02).

a. The Examiner alleges that the prior amendment of the R^{4a} substituent in claim 1 to include “C₃₋₈cycloalkyl” added material to the claims that is broader than the scope of the specification. The Examiner further alleges that the specification only provides support for “cyclohexyl” attached to a methyl, while the prior amendment encompasses a broader scope, including attachment to other groups.

To expedite prosecution, claim 1 has been amended in accordance with the Examiner’s suggestion to remove “C₃₋₈cycloalkyl” from the list of R^{4a} substituents and to include “cyclohexylmethyl” in the list of R⁴ substituents. This amendment is supported by the claims as originally filed, particularly claim 4 and claim 8 (last radical). Additional support is found in the specification at page 15, line 6, wherein it is generically disclosed that R⁴ can be cyclohexylmethyl, at page 17, line 7 and at page 19, line 4. As such, Applicants respectfully submit that the specification provides adequate support for the newly amended definition of R⁴ in claim 1. Accordingly, Applicants respectfully request that the Examiner withdraw this aspect of the rejection under 35 U.S.C. § 112, first paragraph.

b. The Examiner alleges that the prior amendment of the R^{4a} substituent in claim 1 to include “aryl-C₀₋₂alkyl” added material to the claims that is broader than the scope of the specification.

To expedite prosecution, claim 1 has been amended to remove “aryl-C₀₋₂alkyl” from the list of R^{4a} substituents. Accordingly, Applicants respectfully request that the Examiner withdraw this aspect of the rejection under 35 U.S.C. § 112, first paragraph.

c. The Examiner alleges that the prior amendment of the R⁴ substituent to include "aryl-C₀₋₃alkyl" is new matter, as only 0-2 is permitted. During the telephonic interview, the Examiner agreed that the 3 carbon alkylene group present in the second to last R⁴ substituent in claim 8 (*i.e.*, the 3-phenylpropyl group), which is also set forth in the specification at page 17, line 9, together with, for example, the third (methylene group) and forth (ethylene group) R⁴ substituents in claim 8, is sufficient support for the term "aryl-C₀₋₃alkyl," and that this rejection would be overcome by amending the specification to include "aryl-C₀₋₃alkyl" in the definition of R⁴.

To expedite prosecution, the specification has been amended to include "aryl-C₀₋₃alkyl" in the definition of R⁴. In view of the amendments to the specification, Applicants respectfully request that the Examiner withdraw this aspect of the rejection under 35 U.S.C. § 112, first paragraph.

II. INDEFINITENESS REJECTIONS UNDER 35 USC § 112, SECOND PARAGRAPH

Claims 1-6, 11-35, 42 and 44-46 have been rejected under 35 U.S.C § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Applicants respectfully traverse the rejection in view of the comments below.

The test for indefiniteness is "whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity" (MPEP § 2173.02). This analysis does not occur in a vacuum, but rather in view of the following factors: (1) the content of the particular application disclosure; (2) the teachings of the prior art; and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. In addition, "the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope" (MPEP § 2173.02).

1. Use of Commas in the Formulae

The Examiner has requested that the commas be removed from the formulae, such as in "N(A, B)."

To expedite prosecution, Applicants have amended the formulae to remove the commas. Accordingly, Applicants respectfully request that the Examiner withdraw this aspect of the rejection under 35 U.S.C. §112, second paragraph.

2. Use of the Term "Heterocycle" in Claim 1

The Examiner alleges that the definition provided in the specification for "heterocycle" is indefinite, specifically noting the ring size, number and nature of heteroatoms, as well as number and type of rings. During the telephonic interview, the Examiner indicated that this rejection would be overcome by replacing the term "heterocycle" with the term "heterocycloalkyl."

To expedite prosecution, Applicants have amended claim 1 to replace the term "heterocycle" with the term "heterocycloalkyl." Support for the term "heterocycloalkyl" is found in paragraphs 24 and 25 of the specification (*see*, page 6, line 22 through page 7, line 14). Accordingly, Applicants respectfully request that the Examiner withdraw this aspect of the rejection under 35 U.S.C. § 112, second paragraph.

3. Use of the Term "Alkyl" in Claim 1

The Examiner alleges that the use of the term "alkyl" is indefinite, noting that the definition of "alkyl" in the specification is confusing. During the telephonic interview, the Examiner indicated that this rejection would be overcome by amending the definition of "alkyl" provided in paragraph 21 of the specification to refer to "a straight or branched chain hydrocarbon radical having the number of carbon atoms designated (*i.e.* C₁-C₁₀ means one to ten carbons).

To expedite prosecution, Applicants have amended the definition of "alkyl" in accordance with the Examiner's suggestion. In addition, since Applicants intended the term "alkyl" to include "alkenyls" (hydrocarbons containing one or more double bonds), "alkynyls"

(hydrocarbons containing one or more triple bonds) and “cycloalkyls” (cyclic hydrocarbons) when the application was originally filed, Applicants have removed these terms from the definition of “alkyl,” but have added a separate definition for such groups. The amendments to the specification obviate the Examiner’s concerns. Accordingly, Applicants urge the Examiner to withdraw this aspect of the rejection under 35 U.S.C. § 112, second paragraph.

4. Use of the Terms “Aryl” and “Heteroaryl” in Claim 1.

The Examiner alleges that the use of the term “aryl” in claim 1 is indefinite, noting that the definitions of “aryl” and “heteroaryl” in the specification are confusing. During the telephonic interview, the Examiner indicated that this rejection would be overcome by amending the definition of “aryl” provided in paragraph 27 of the specification to refer to “an aromatic, hydrocarbon substituent, which can be a single ring or multiple rings (up to three rings), which are fused together or linked covalently.”

To expedite prosecution, Applicants have amended the definition of “aryl” and, in turn, “heteroaryl” in accordance with the Examiner’s suggestion. The amendment to the specification obviates the Examiner’s concerns. Accordingly, Applicants urge the Examiner to withdraw this aspect of the rejection under 35 U.S.C. § 112, second paragraph.

III. ENABLEMENT REJECTION UNDER 35 USC § 112, FIRST PARAGRAPH

Claims 8-9 have been rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicants respectfully traverse the rejection.

The test for enablement is whether the experimentation needed to practice the invention is undue or unreasonable (*Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916)) such that “the disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention” (MPEP § 2164.01).

In support of this rejection, the Examiner alleges that the third choice in claim 8, the last two choices in claim 8 and the sixth to last choice in claim 9 do not fall within Formula I,

and thus are not enabled by the specification. As explained above, this issue was discussed with the Examiner during the telephonic interview, and the Examiner agreed that the 3 carbon alkylene group present in the second to last R⁴ substituent in claim 8 (*i.e.*, the 3-phenylpropyl group), which is also set forth on page 17, line 9 of the specification, together with, for example, the third (methylene group) and forth (ethylene group) R⁴ substituents in claim 8, is sufficient support for the term "aryl-C₀₋₃alkyl," and that this rejection would be overcome by amending the specification to include "aryl-C₀₋₃alkyl" in the definition of R⁴.

As pointed out above, to expedite prosecution, the specification has been amended to include "aryl-C₀₋₃alkyl" in the definition of R⁴. In view of the amendments to the specification, Applicants respectfully request that the Examiner withdraw the enablement rejection under 35 U.S.C. § 112, first paragraph.

IV. OBJECTION TO THE ABSTRACT

In the Office Action, the Examiner has objected to the abstract as too vague, and has suggested incorporating therein the definitions of R⁴ and R⁶. In accordance with the Examiner's suggestion, Applicants have amended the abstract to incorporate the definitions of R⁴, R⁵ and R⁶ as filed. Accordingly, Applicants respectfully request that the Examiner withdraw the objection to the abstract.

Appl. No. 10/687,220
Amdt. dated March 31, 2006
Reply to Office Action of June 22, 2005

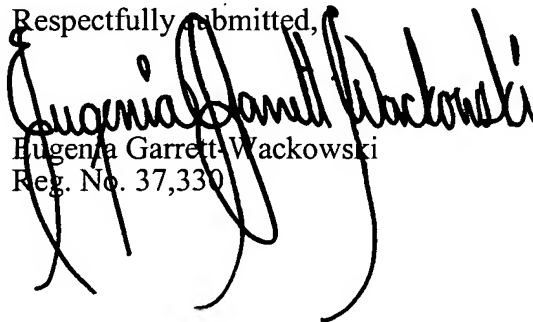
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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 925-472-5000.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Eugenia Garrett Wackowski', is written over the typed name and registration number.

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